

**510(k) Summary**

JUL 22 2011

The following 510(k) summary is being submitted as required by 21 CFR 807.92(a):

**1. Submission Information**

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- **Applicant:** L&K BIOMED Co., Ltd.  
Address: Room1104, ACE High-End Tower3, 371-50, Gasan-dong,  
Geumcheon-gu, Seoul, 153-803 Republic of Korea  
Phone No: 82-2-2624-1471  
Fax: 82-2-2624-1477
- **Manufacturer:** L&K BIOMED Co., Ltd.  
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Geumcheon-gu, Seoul, 153-803 Republic of Korea  
Phone No: 82-2-2624-1471  
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- **Official Correspondent:** Hee-kyeong Joo  
Address: Room1104, ACE High-End Tower3, 371-50, Gasan-dong,  
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Phone No: 82-2-2624-1471  
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- Date Prepared: July 04, 2011

**2. Device Identification**

Trade Name	LEXUS Cervical Fixation System (TRIUS Cervical Fixation System )
Common Name	Spinal Fixation System
Classification Name	Pedicle Screw Spinal System (21CFR888.3070) Spinal Interlaminar Fixation Orthosis (21CFR888.3050)
Product Code	MN1, KWP
Device Class	Class II

**3. Predicate or legally marketed devices which are substantially equivalent**

- Spinal Concept, Inc. / Nex-Link Spinal Fixation (K031985)
- Aesculap, Inc. / S4 Spinal Fixation (K050979, K060152)
- Medtronic Sofamor Danek USA, Inc. / VERTEX<sup>TM</sup> Reconstruction System (K003780)

#### 4. Device Description

The LEXUS Cervical Spinal Fixation System is a top-loading, multiple component, posterior (cervical-thoracic) spinal fixation system which consists of polyaxial screws, rods, set screws, and hooks.

**Materials:** All products are made of titanium alloy (Ti-6Al-4V ELI) in conformance with ASTM F136) approved for medical use.

#### 5. Indications for Use

The LEXUS Cervical Fixation System is indicated for the following:

- DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spinal stenosis
- Fracture/dislocation
- Failed previous fusion
- Tumors

The implants are intended to provide stabilization as an adjunct to fusion when used with autogenous bone graft or allograft following the reduction of fractures/dislocations or trauma in the spine.

Hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1 –T3) spine.

The pedicle screws are limited to placement in T1 -T3 in treating thoracic conditions only. The pedicle screws are not intended to be placed in or treat conditions involving the cervical spine.

#### 6. Performance Data

The LEXUS Cervical Fixation System is tested according to the ASTM F1717, specifically, Static and Dynamic Axial Compression, Static Tension and Static Torsion.

#### 7. Comparison of the technological characteristics of the device to predicate and legally marketed devices

The LEXUS Cervical Fixation System is considered substantially equivalent to other legally marketed devices. They are similar in design, material, and indications for use and are expected to be equivalent in safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

L&K BIOMED Co., Ltd.  
% Ms. Hee Kyeong Joo  
Room 1104, ACE High-End Tower 3  
371-50, Gasan-dong, Geumcheon-gu,  
Seoul, 153-803  
Republic of Korea

JUL 22 2011

Re: K103414  
Trade Name: LEXUS Cervical Fixation System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class II  
Product Code: MNI, KWP  
Dated: July 05, 2011  
Received: July 08, 2011

Dear Ms. Joo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may; therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

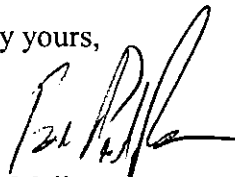
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K 103414

**Indications for Use Statement****510(k) Number (if known):** K103414**Device Name:** LEXUS Cervical Fixation System**Indications For Use:**

The LEXUS Cervical Fixation System is indicated for the following:

- DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spinal stenosis
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The implants are intended to provide stabilization as an adjunct to fusion when used with autogenous bone graft or allograft following the reduction of fractures/dislocations or trauma in the spine.

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The pedicle screws are limited to placement in T1 -T3 in treating thoracic conditions only. The pedicle screws are not intended to be placed in or treat conditions involving the cervical spine.

Prescription Use   ✓   AND/OR Over-The-Counter Use           

(Part 21 CER801 Subpart D)

(21 CER801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (OED)

(Division Sign-Off)

Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number   K103414